

***Examiner's Response***

Applicant's response on April 25, 2008 filed in response to the Election/Restriction dated April 25, 2008 has been received and duly noted. The Examiner acknowledges Applicants' election of Group I without traverse. For the record, the restriction requirement has been attached to this response as shown below.

The Examiner acknowledges Applicant's amendments to the claims after a telephone interview dated April 21, 2008.

The restriction between compound claims of Group I and corresponding method claims of Group III was withdrawn and rejoined. The Applicant has cancelled the corresponding method claims.

There was no prior art made of record. The point of novelty in claimed genus is the R1 being -CH=CH-R5 of Formula I.

In view of the Applicant's election to the restriction requirement and amendments to the claims, this case is found allowable.

The method claims 24-27 were rejoined and cancelled.

Claims 1, 4-14 and 16-17 are allowable.

**DETAILED ACTION**

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-14 and 16-17 are drawn to compounds and pharmaceutical compositions of Formula I, wherein R5=cyano, CO<sub>2</sub>H, CONR<sub>6</sub>R<sub>7</sub> where R<sub>6</sub> and R<sub>7</sub>=H, unsubstituted alkyl, and can combine with the N to form piperidinyl, R<sub>2</sub>=H, hydroxyl, alkoxy, halogen, haloalkyl, R<sub>3</sub>=H, hydroxyl, alkoxy, halogen, haloalkyl, unsubstituted alkyl, phenyl and R<sub>4</sub>=H, haloalkyl, hydroxyl, alkoxy. A further election of single disclosed species is required.
- II. Claims 1-13 and 16-17 are drawn to compounds and pharmaceutical compositions of Formula I that are not encompassed by group I. A further election of single disclosed species is required.
- III. Claims 24-27 are drawn to a method of eliciting a biological or medical response of a tissue, system, an animal or human that responds to selective estrogen receptor modulation, a method of healing, treating, preventing of a disease, disorder, condition or side effect that responds to selective estrogen receptor

modulation and treatment and preventing of listed diseases and conditions by Applicant limited to the scope of one of groups I-II. An election of species is required if this group is chosen.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

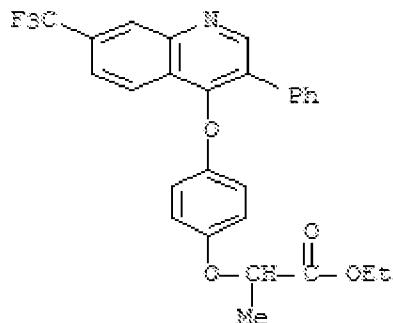
The special technical feature corresponding to Group I is a substituted quinoline structure wherein R5=cyano, CO<sub>2</sub>H, CONR<sub>6</sub>R<sub>7</sub> where R<sub>6</sub> and R<sub>7</sub>=H, unsubstituted alkyl, and can combine with the N to form piperidinyl, R<sub>2</sub>= H, hydroxyl, alkoxy, halogen, haloalkyl, R<sub>3</sub>=H, hydroxyl, alkoxy, halogen, haloalkyl, unsubstituted alkyl, phenyl and R<sub>4</sub>=H, haloalkyl, hydroxyl, alkoxy. Group II contains a substituted quinoline structure as its special technical feature that is not encompassed by group I. These systems are not considered equivalent.

The technical feature corresponding to the methods claims of Group III is a method of eliciting a biological or medical response of a tissue, system, an animal or human that responds to selective estrogen receptor modulation, a method of healing, treating, preventing of a disease, disorder, condition or side effect that responds to

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selective estrogen receptor modulation and treatment and preventing of listed diseases and conditions by Applicant limited to the scope of one of groups I-II. There is a significant difference in the between compounds/composition and methods of treating a disease/condition. These treatments of diseases/conditions and compounds/compositions are not considered equivalent.

The special technical feature of this invention is the common core found in Formula I. This special technical feature, found in DE 3101544 A1 as described by Mildenberger et al (compound 11, page 14).



Therefore the above claims, are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a common core structure and the technical features present fail to define a contribution over the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to only one invention.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### ***Election***

During a telephone conversation with Attorney J. Scott Young on April 16, 2008 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14 and 16-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

### ***Rejoinder Advisory***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

The method claims 24-27 were rejoined and cancelled.

Claims 1, 4-14 and 16-17 are allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry, PhD/  
Examiner  
Art Unit 1625

/Rita J. Desai/  
Primary Examiner, Art Unit 1625